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May 23, 2001

## BY FEDERAL EXPRESS

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

Re: Docket No. 01D-0058  
Notice, Request for Comments

To Whom It May Concern:

The National Nutritional Foods Association ("NNFA") is submitting this comment to the Food and Drug Administration ("FDA") in response to the February 22, 2001, *Notice; request for comments* regarding the need for further guidance on structure/function claims.

NNFA is a trade association representing the interests of more than 1,000 manufacturers, suppliers and distributors and 3,000 retailers of natural foods, dietary supplements and other natural products throughout the United States. The Association has been actively involved in monitoring the progress of the Dietary Supplement Health and Education Act ("DSHEA") and FDA's regulations promulgated under DSHEA, including regulations regarding what is an appropriate "structure/function" statement and what is a disease claim.

While NNFA recognizes that FDA has committed to providing further guidance on this issue, NNFA does not believe it is necessary at this time. NNFA suggests that the lengthy preamble to the final "structure/function" rule published on January 6, 2000, and the numerous courtesy letters since that date, serve as guidance to the industry, and that further word from the Agency in the form of a guidance document is not necessary at this point.

NNFA's comment that no guidance is necessary at this time should not be taken as implying that FDA does not have adequate oversight over these claims. NNFA recognizes that the Office of Inspector General is currently assessing the effectiveness of FDA's supplement labeling oversight and usefulness of product claims/disclaimers for the elderly and their

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practitioners. The absence of a specific guidance on this issue should not in any way indicate a lack of appropriate review of "structure/function" claims by FDA. FDA has a procedure in place to review notification letters from companies and to issue courtesy letters in response which provide additional guidance for the industry. "Structure/function" claims are not lacking appropriate review.

For the foregoing reasons, we respectfully submit this comment to FDA's February 22, 2001, notice.

Respectfully submitted,

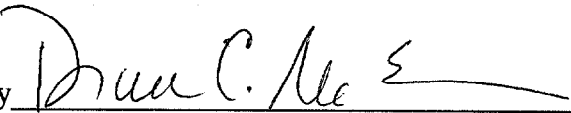
NATIONAL NUTRITIONAL FOODS ASSOCIATION

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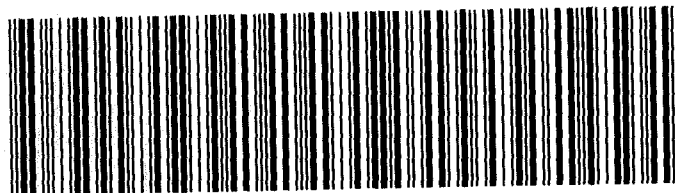
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